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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,221	08/22/2006	Donald Darkin	4398-537	1297
23117 7590 07/06/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
BLIZZARD, CHRISTOPHER JAMES				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/579,221

**Applicant(s)**

DARKIN ET AL.

**Examiner**

CHRISTOPHER BLIZZARD

**Art Unit**

3771

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 27, 28, 36, 37, 43, 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26, 29-35, 38-42 and 44-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to amendment filed 3/24/10. As directed claims 29, and 30 were amended, claims 32-50 were added, claims 27 and 28 were withdrawn and no claims were cancelled. Therefore this application currently has claims 1-50 are pending.

### ***Election/Restrictions***

2. Newly submitted claims 36, 37, 43, 49 and 50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are drawn to a species that includes vent assembly comprising a cylinder and a sleeve to be attached below and elbow, which can be seen in figure 6. The previous elected species is directed to a vent assembly found on the mask or on the elbow as seen in figures 24 or 25a. The claims previously presented claims drawn to the elected species are claims 3 and 8.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36, 37, 43, 49 and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Drawings***

3. The drawings were received on 3/24/10. These drawings are not acceptable because they introduce new matter which was not present in the originally filed specification or drawings.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "nozzle elements", must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The amendment filed 3/24/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material

which is not supported by the original disclosure is as follows: The nozzles (211) found in amended paragraph [0069].

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4, 15, 16, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose how nozzle elements are part of a mask assembly.

To any extent the claims are understood and appear to be supported by a clear and complete disclosure, the following appears to be appropriate.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 29, 33, 40, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 29 recites the limitation "the flow of exhaled gas from the patient" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Regarding claims 33, 40, and 46, the limitation "wherein a number of the plurality of first vent holes is less than a number of the plurality of second vent holes" renders the claim indefinites as it fails to further limit the invention because a number of the plurality of second vent holes can always be 2, and a number of a plurality of first holes can always be 1, which is less than 2.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 4 as best understood are rejected under 35 U.S.C. 102(b) as being anticipated by Humphries (1,125,542).

14. Regarding claims 1 and 4 Humphries discloses what is inherently a nasal mask assembly in that it covers the nostrils of a patient. Claim 4 recites "the cushion includes nozzle elements" which is assumed to be a nozzle element to be inserted into the nostrils. Broadly, the assembly of Humphries is a mask assembly for the nostrils. The Humphries assembly also includes a frame (a, b), a cushion in the form of two nozzle elements (e) to be inserted into the nostrils of a user, and a vent assembly including a

first vent (s) and a second vent (u) wherein a clip (o) slides around the frame to select between the two vents (page 2, lines 4-15).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5-26, 29-35, 38-42, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauman (4,821,713) in view of Gradon (6,662,803).
2. Regarding claims 1 and 17, Bauman discloses a mask assembly for a patient (fig. 1) comprising a vent assembly (fig. 11) including a first vent (127) and a second vent (126) and a selector switch (121) to switch the flow of exhaled gas from the patient between the first and second vents (column 4, lines 62-65). Bauman does not disclose the mask assembly having a frame and a cushion provided to the frame. Gradon teaches a mask assembly with a vent assembly (300) and a frame that is a shell (102) with a cushion (104). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask assembly of Bauman with a frame and cushion as taught by Gradon in order to provide the advantage of a more comfortable mask.
3. Regarding claims 2 and 18, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the vents having different flow characteristics (column 5, lines 3-20)

4. Regarding claim 3, the combination of Bauman and Gradon teach the claimed invention wherein Gradon teaches the vents assembly being provided on the shell (fig. 1).
5. Regarding claims 5-7, 19, and 29, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the selector switch that slides around a pivot point as it is rotated to different vent positions (column 5, lines 3-4) and is therefore rotatable, pivottable and slidable.
6. Regarding claims 8 and 9, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the selector being on a dependant arm of an elbow (fig 10).
7. Regarding claims 10 and 20, the combination of Bauman and Gradon teach the claimed invention wherein Gradon teaches the covering of vents with a material configured to reduce noise (column 5, lines 16-22).
8. Regarding claim 11 and 21, the combination of Bauman and Gradon teach except for the filter material being foam, porous polytetrafluorethylene, or ceramic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the filter material be foam, porous polytetrafluorethylene, or ceramic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.
9. Regarding claims 12-14 and 22-24, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the selector having positioning



structure in the form of detents (121b, 122) to hold the switch in a place correspond to the multiple vents (column 4, lines 62-68) and allows exhaled gas to be vented even if the vent assembly is not in the first or second position (fig 11).

10. Regarding claims 15, 16, 25 and 26 the combination of Bauman and Gradon teach the claimed invention wherein Gradon teaches an alarm in the form of a higher noise level produced by the vent assembly (column 5, lines 14-21), therefore it would have been obvious to provide the third vent (125) a Bauman with an alarm as taught by Gradon in order to provide the advantage of notify the user if the device isn't working properly.

11. Regarding claims 30, 38 and 44, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the first vent including two vent holes (127, 123) and the second vent including two vent holes (126, 123).

12. Regarding claim 31, the combination of Bauman and Gradon teach the claimed invention wherein Gradon teaches the vent assembly extending from the inner surface of the frame to the out surface of the frame (fig. 7).

13. Regarding claims 32, 39, and 45, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the first vent including a vent hole of a first size (127) that is larger than a vent hole of the second vent having second size (126).

14. Regarding claims 34, 41 and 47, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the second vent reducing the flow compared to the first vent, but does not disclose the second vent reducing the flow by

about 5-50% compared to the first vent. It would have been obvious to one of ordinary skill in the art at the time of the that this reduction of flow could be about 5-50% compared to the first vent in order to provide the advantage of using the device with people of different lung capacities since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Regarding claims 35, 42, and 48, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches the vents having different flows (column 5, lines 3-20), but does not disclose the specific flows being 45-55 l/min and 55-65 l/min. It would have been obvious to one of ordinary skill in the art at the time of the invention to have the flow of gas through the different vents be 45-55 l/min and 55-65 l/min in order to provide the advantage of using the device with people of different lung capacities since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

16. Regarding claims 33, 40, and 46, the combination of Bauman and Gradon teach the claimed invention wherein Bauman teaches a number of the plurality of second vent holes being 2, and a number of a plurality of first holes can always be 1, of the two vent hole, which is less than the 2 of the second vent.

### ***Response to Arguments***

17. Applicant's arguments filed 3/24/10 have been fully considered but they are not persuasive. Applicant's arguments in regards to Humphries not disclosing a vent

assembly with a selector switch is not persuasive because when the vents (u, p) are line and the patient exhales gas would initial exhaust out of these vents, if the element (o) is switched so that the vents (u,p) do not align then the flow would be switched to vents (s). Applicant's argument that Bauman does not disclose the claimed vent assembly is not persuasive because during use of the device of Bauman at the onset of exhalation a flow of gas would flow through air bleed means (120) before the closing of valve (32), it is this very flow of exhaled gas that cause the closure of valve (32).

### ***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday-Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Christopher Blizzard/  
Examiner, Art Unit 3771

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